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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,130	12/03/2001	Takahide Kishimoto	2356/10	4623

7590 12/18/2003

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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,130

Applicant(s)

KISHIMOTO ET AL.

Examiner

Louise N. Leary

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54-57 is/are allowed.
- 6) ☒ Claim(s) 1-6, 19-53 and 58-78 is/are rejected.
- 7) ☒ Claim(s) 7-18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

1. Claims 1-78 are pending in this application.

2. OBJECTION TO THE SPECIFICATION:

The specification is objected to because the meaning intended for the phrase “and the like” can not be determined. Alternatively, the phrase “and the like” includes elements not actually disclosed by the original specification. Correction is required.

3. Claims 1, 3, 19-53, 58-69, and 70-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In all occurrences, the claims are indefinite because it is unclear if “(pH 7.5, 30 min)” is part of the “heat stability” claim limitation.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step correlating “determining homocysteine” with “measuring the resulting compound”. Alternatively, the claim 19 is indefinite for omitting the chemical name of “the resulting compound” measured.

Claims 70-78 are indefinite due to the omission of instructions for using the kits claimed in the present invention.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over van Dijken et al (Archives of microbiology, V 111(1-2), pp 77-83, (Dec. 1976)(Abstract Only).

van Dijken et al disclose an enzymatic method for analyzing formaldehyde dehydrogenase derived from *Hansenula* yeast. Specifically, van Dijken et al disclose “[Formaldehyde dehydrogenase was strictly dependent on NAD and glutathione for activity.]” Also, with respect to the physico-chemical properties described in instant claim 2, van Dijken et al disclose “[The enzyme catalyzed the glutathione-dependent oxidation of formaldehyde to S-formylglutathione.]” In regards to the pH ranges set forth in the instant claims, van Dijken et al disclose “[The reaction was shown to be reversible: at pH 8.0 a Km of 1 mM for S-formylglutathione was estimated for the reduction of the thiol ester with NADH]”. Regarding the “heat stability” limitations claimed, van Dijken et al disclose or suggest method steps for determining heat stability of the dehydrogenase derived from *Hansenula polymorpha*. See the entire abstract.

Thus, van Dijken et al disclose or suggest the method claimed except for stating "having a ratio of reactivity with thio-NAD to reactivity with NAD of not less than 30%" is a characteristic of the enzyme.

However, with respect to the instant claim limitation, "having a ratio of reactivity with thio-NAD to reactivity with NAD of not less than 30%", van Dijken et al disclose or suggest invention claimed except for addressing a ratio of reactivity for the enzyme which is deemed to be an inherent property. Hence, van Dijken et al disclose all the claim limitations except for the inherent property of the dehydrogenase "having a ratio of reactivity with thio-NAD to reactivity with NAD of not less than 30%" which anticipates or renders obvious the invention claimed.

The burden of proof is on applicants to show patentably distinct differences between the van Dijken et al reference and the present invention as claimed.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrow (US 5,668,173).

Garrow discloses a method for determining homocysteine levels in a sample using betaine-homocysteine methyltransferase. Garrow discloses "[Betaine, a metabolite of choline oxidation, is a substrate for an enzyme called betaine-

homocysteine methyltransferase. Betaine-homocysteine methyltransferase catalyzes the conversion of betaine and homocysteine to dimethylglycine and methionine, respectively.]” See column 2, lines 10-15 and this entire document.

6. Claims 7-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 54-57 are allowable over the prior art of record.

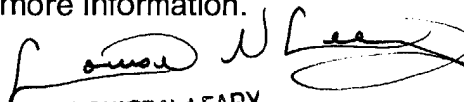
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 10 to 6:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

December 9, 2003